HAND SANITIZER- alcohol gel Batallure Beauty LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Hand Sanitizer

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes. In case of contact with eyes, rinse eyes thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Children under 6 years of age should be supervised when using this product to avoid swallowing.

Other information

Store between 15-30°C (59-86°F) Avoid freezing and excessive heat above 40°C (104°F) May discolor some fabrics. Harmful to wood finishes and plastics

Inactive ingredients

Water (Aqua), Aloe barbadensis leaf extract, Acrylates/C10-30 alkyl acrylate crosspolymer, Fragrance, Triethanolamine

Package Label - Principal Display Panel



236 mL NDC: 76786-074-03

HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76786-074

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL (UNII: 3K9958V90M) ALCOHOL 70 mL in 100 mL

| Inactive Ingredients | | | | |
|---|----------|--|--|--|
| Ingredient Name | Strength | | | |
| CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO) | | | | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| TROLAMINE (UNII: 903K93S3TK) | | | | |

| P | Packaging | | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:76786- 074-03 | 236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 01/18/2021 | | | |

| Marketing Information | | | |
|-------------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A | 01/18/2021 | 11/01/2022 |
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Labeler - Batallure Beauty LLC (790417534)

Revised: 11/2021 Batallure Beauty LLC